

### **Remarks**

The Applicants have amended Claims 1 and 2 to correct minor typographical errors. Entry into the official file is respectfully requested.

The Applicants note with appreciation the withdrawal of the previous rejection under 35 USC §112.

Claims 1-11 stand rejected under 35 USC §102 as being anticipated by Hind as evidenced by Medline. The Applicants note with appreciation the Examiner's detailed comments hypothetically applying Hind and Medline against Claims 1-7. The Applicants respectfully submit, however, that Hind as evidenced by Medline fails to explicitly or implicitly disclose all of the subject matter of those claims. Detailed reasons are set forth below.

Hind discloses the treatment of pain associated with herpes-zoster infection and post-herpetic neuralgia (PHN). That treatment of pain is conducted with an effective dosage of lidocaine intradermally for an extended period of time.

The rejection turns to Medline for evidence that symptoms of post-herpetic neuralgia include pain and numbness of the affected skin area. This teaching by Medline is used to support the proposition that Hind inherently treats any neuropathically-induced negative sensory phenomenon such as numbness because it is a symptom and is associated with the disorder. There are, however, several problems with the utilization of Medline.

First, there is no evidence on the record that Medline is prior art. In fact, the Applicants respectfully submit that the evidence on the record is that Medline was obtained on January 12, 2009 and apparently has a publication date of September 7, 2006. The Applicants respectfully submit that assuming the earlier publication date of September 7, 2006 is "effective," that publication date is far, far too late to be the prior art relative to the Applicants' November 25, 2003 date. Therefore, the Applicants respectfully submit that Medline may not be used under §102 alone or as a supporting document for Hind. On this basis alone, the Applicants respectfully submit that the rejection must fail.

However, there is another problem with the rejection. Medline is directed to neuralgia generally. The teachings of Hind are directed to post-herpetic neuralgia. There is nothing in Medline that indicates that numbness is a symptom of post-herpetic neuralgia. Of course, there are many types of neuralgia other than post-herpetic neuralgia. Thus, there is no disclosure in Medline

that the mentioned numbness is applicable to post-herpetic neuralgia. It is only speculation based on Medline that numbness would be associated with a specific type of neuralgia such as post-herpetic neuralgia. Also, there is nothing in Hind that indicates that numbness is a symptom of post-herpetic neuralgia. Thus, this is yet another reason why Medline is inapplicable alone or as evidenced by Hind.

There is still a further problem with respect to the conclusion that Hind inherently treats numbness. First, the Applicants have carefully considered the entire Hind disclosure and there is no disclosure concerning the treatment of numbness. There is only disclosure associated with treating pain. This failure to disclose treating numbness is apparently the reason for the reliance on inherency. This reliance is, however, flawed inasmuch as pain and numbness are essentially mutually exclusive symptomologies. If one experiences pain, one seeks treatment to relieve the pain which is the subject matter of Hind. Hind recognizes that post-herpetic neuralgia causes pain and provides a method of treating that pain.

On the other hand, when a person experiences numbness, there is no pain. In fact, the Applicants respectfully submit that numbness is an effect or symptom that often accompanies the blockage of pain. The classic case is when a patient undergoes a dental treatment such as filling a cavity or a similar procedure that is anticipated to be painful. The dentist administers an effective dosage of a substance that induces numbness so that there will be no pain or, said differently, the dentist administers an effective dosage of painkiller that has numbness as a side effect. Thus, the dental treatment that would otherwise cause serious pain does not cause pain because of the pre-administration of the effective dosage. The patient experiences numbness in that instance, but not pain. It also inherently follows that one skilled in the art would not administer more of the substance to the patient to alleviate or treat the numbness.

What this means with respect to the rejection is that there is no inherent treatment of numbness when looking to Hind because Hind administers an effective dosage to treat pain. This is illustrated in the attached package insert for Lidoderm<sup>®</sup>, which is "for the relief of pain associated with post-herpetic neuralgia." There is no indication for the treatment of numbness. In any event, there would be no need to treat pain if the patient was experiencing numbness because the pain would be masked by the numbness. Said differently, the patient experiences pain or the patient experiences numbness, but does not experience both simultaneously. Therefore, looking to the

disclosure of Hind which relates to the treatment of pain, there would be no inherency of treating numbness when utilizing the Hind disclosure of treating pain because there is no numbness present when pain is present and in need of treatment. Therefore, the Applicants respectfully submit that there is no inherent treatment of numbness by the disclosure of Hind. Withdrawal of the rejection is respectfully requested.

Claims 1-11 stand rejected under 35 USC §103 over the combination of Wolicki with Hind as evidenced by Medline. The Applicants respectfully submit that they have already established that Medline is not prior art and thus not eligible for utilization in the rejection. The Applicants have also established that Hind is inapplicable to Claims 1-11 because it does not disclose inherent treatment of numbness because numbness means that there is no pain present which means that one skilled in the art would not utilize the Hind pain treatment method.

The Applicants also respectfully submit that Wolicki fails to provide additional teachings, disclosure or suggestions that would cure the deficiencies set forth above with respect to Hind and Medline. In other words, even if one skilled in the art were to hypothetically combine Wolicki with Hind, the result would still be the same, the methodology associated with the Wolicki/Hind combination would still be different from what the Applicants claim. Withdrawal of the rejection of Claims 1-11 is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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